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EXAMINER

MAKIS

ART UNIT

PAPER NUMBER

1301

9

DATE MAILED: 12/10/97

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

OFFICE ACTION SUMMARY

Responsive to communication(s) filed on 9-5-97
 This action is FINAL.

Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 D.C. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

Claim(s) 15-29 is/are pending in the application.
Of the above, claim(s) 18, 19 and 23-29 (as directed to species #2) is/are withdrawn from consideration.
 Claim(s) _____ is/are allowed.
 Claim(s) 15-17, 20-22 and 23-29 (as directed to species #1) is/are rejected.
 Claim(s) _____ is/are objected to.
 Claim(s) _____ are subject to restriction or election requirement.

Application Papers

See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
 The drawing(s) filed on _____ is/are objected to by the Examiner.
 The proposed drawing correction, filed on _____ is approved disapproved.
 The specification is objected to by the Examiner.
 The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
 All Some* None of the CERTIFIED copies of the priority documents have been
 received.
 received in Application No. (Series Code/Serial Number) _____
 received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

Notice of Reference Cited, PTO-892
 Information Disclosure Statement(s), PTO-1449, Paper No(s). _____
 Interview Summary, PTO-413
 Notice of Draftsperson's Patent Drawing Review, PTO-948
 Notice of Informal Patent Application, PTO-152

-SEE OFFICE ACTION ON THE FOLLOWING PAGES-

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1) Claims 20-29 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claims 23, 24 and 26-29, there is no antecedent basis for "the material parts".

In claim 25, the step of adhering the elastomeric composition "by contact to the tube and stent" is awkward / ambiguous.

Claims 23-29 are indefinite because (1) applicant considers claims 23-29 to be directed to the elected species whereas (2) the examiner considers claims 23-29 to be directed to the non-elected species. Each of claims 23-29 are a non-sequitur since each of these claims is a "species dependent on a species".

2) Claims 15-17 and 20-29 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

As to claims 15-17 and 20-22, the step of "radially expanding at least the portion of the stent in the tube or

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allowing at least the portion of the stent to expand in the tube" (emphasis added) as set forth in claims 15-17 and 20-22 is not reasonably conveyed by the original specification (is new matter) since the original specification only supports allowing the stent to radially expand.

As to claims 23-29, (1) the combination of the limitation of claims 23-29 and (2) claims 15-17 and 20-22 is not reasonably conveyed by the original specification since the original specification fails to describe combining species #1 and species #2 in such a manner. Claims 23-29, which are dependent on claims 15-17 and 20-22, are directed to species #2 (method for covering a stent including removing stent from tube / surface) whereas claims 15-17 and 20-22 are directed to species #1 (method for covering a stent including adhering the stent to a tube using chemical bonding or using curable adhesive or using elastomeric composition dissolved in solvent). For support for claims 23-29, applicant directs the examiner's attention to page 4 lines 27 - page 5 line 15, figures 1 and 2, page 5 lines 34 - page 6 line 2 and page 6 lines 25-28. These portions of the specification describe species # 2 instead of species #1. The description at page 4 lines 27 - page 5 line 15 and page 5 line 34 - page 6 line 2 is a continuation of the description of the process in which

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lifting medium 7 (illustrated in figure 2) is used. When lifting medium 7 is used the tube is not bonded to the stent as is required by each of the independent claims 15-17 and 20-22. The description at page 6 lines 24-30 is not relevant since that description fails to describe the claimed sequence of steps in claim 25. Hence, the specification fails to reasonably convey the species limitation as in claims 23-29 with the species #1 independent claims 15-17 and 20-22. Furthermore, the specification provides no guidance as to how such a limitation of shaping the covering is to be done when as in species #1 the covering is provided as a preformed covering into which the stent is inserted instead being formed insitu on the stent using a coating technique as in species #2.

3) Claims 23, 24 and 26-29 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The specification fails to enable performing the limitation of claims 23, 24 and 26-29 in combination with the methods of independent claims 15-17 and 20-22. The specification provides no guidance as to how such a limitation of shaping the covering

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as in claims 23, 24 and 26-29 is to be done when as in species #1 the covering is provided as a preformed covering into which the stent is inserted instead being formed insitu on the stent using a coating technique as in species #2.

4) The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5) Claims 15-17 and 20-29 are rejected under 35 U.S.C. 103(a) as being unpatentable over MacGregor (US Patent 5,015,253) in view of Gianturco (US Patent 5,282,824) and Kaster (US Patent 4,444,215) and optionally further in view of Simon et al (US Patent 5,384,308).¹

MacGregor teaches that in one method of deploying, stents are compressed circumferentially so that it may be fitted within a tubular body, such as a catheter and subsequently the stent is expanded (column 1 line 65-column 2 line 50). MacGregor teaches

¹Claims 23-29 are examined on the merits only to the extent that they define subject matter of the elected species. Claims 23-29 have not been examined to the extent that they are directed to species #2. Note above 112 rejections.

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applying or bonding an appropriate coating directly to the exterior surface of the stent 21 (column 5 lines 51-60).

MacGregor does not specifically recite covering the stent with a preformed tubular cover.

As to claims 15-17 and 20-29, it would have been obvious to one of ordinary skill in the art to position the stent 21 of MacGregor within a preformed cover and to bond the preformed cover to the stent since:

(A) MacGregor suggests applying or bonding a coating (covering) to the stent;

(B) Gianturco suggests covering a stent with a preformed sleeve; and

(C) Gianturco and Kaster suggest bonding covering material to a stent.

The limitation of the material of the covering being elastomeric (claims 15-17) or polymer (claims 20-22) would have been obvious to one of ordinary skill in the art since it is conventional to make covering material for a stent out of elastic / polymer material as evidenced by Gianturco (abstract), Kaster (column 6 lines 25-44, column 7 lines 12-25) and optionally Simon et al (column 4 lines 27-47); it being noted that Simon et al is

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also further evidence of a suggestion to use a preformed cover for a stent.

As to the technique used to assemble the stent and the preformed tube as set forth in claims 15-17 and 20-22, it would have been obvious to one of ordinary skill in the art to compress the stent, insert the stent into the preformed cover and expand the stent within the preformed cover so as to position the stent within the preformed cover since MacGregor suggests facilitating assembly of the stent within another tube by compressing the stent and inserting the compressed stent into the another tube.

As to the type of bonding in claims 15 and 20, it would have been obvious to one of ordinary skill in the art to bond using "chemical bonding" in view of the above noted suggestion from Gianturco and Kaster to bond covering material to a stent.

As to the type of bonding in claims 16 and 21, it would have been obvious to one of ordinary skill in the art to bond using a "curable adhesive medium" in view of (a) the above noted suggestion from Gianturco and Kaster to bond covering material to a stent, (b) it is taken as well known / conventional in the bonding art to bond a first tubular member to another tubular member by coating the inside of the first tubular member with adhesive and then to insert the second tubular member into the

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first tubular member and (c) "curable adhesive medium", which is cured to effect bonding, is taken as a well known / conventional type of adhesive in the bonding art.

As to the type of bonding in claims 17 and 22, it would have been obvious to one of ordinary skill in the art to bond using "elastomeric composition dissolved in solvent" in view of (a) the above noted suggestion from Gianturco and Kaster to bond covering material to a stent, (b) it is taken as well known / conventional in the bonding art to bond a first tubular member to another tubular member by coating the inside of the first tubular member with adhesive and then to insert the second tubular member into the first tubular member and (c) "elastomeric composition dissolved in solvent", which is has the solvent evaporized and the elastomer composition polymerized is taken as a well known / conventional type of adhesive in the bonding art.

6) REMARKS

Applicant's arguments with respect to claims 23-29 have been considered but are moot in view of the new ground(s) of rejection.

Applicant's arguments filed 9-5-97 have been fully considered but they are not persuasive.

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Applicant's arguments regarding the 112 first paragraph rejection are not persuasive since issue is whether or not the originally filed disclosure would have conveyed to one of ordinary skill in the art that appellant had possession of the concept of what is claimed instead of whether or not the concept is known to those in the art.

Applicant's arguments regarding the 103 rejection are not persuasive since when considered as a whole the prior art (MacGregor, Gianturco and the optional reference Simon) teach those of ordinary skill in the art that a preformed covering is an alternative covering material to a covering formed by coating and that when using a covering on a stent, the covering should be bonded to the stent (MacGregor, Gianturco and Kaster).

With respect to applicant's argument that the stent of MacGregor cannot be bonded to the tubular body, the examiner merely notes that the reference to MacGregor's teachings as to the tubular body was for the purpose of citing evidence that one of ordinary skill in the stent art knows that radially contracting a stent facilitates insertion of the stent into a tube; it being noted that one of ordinary skill in the art readily understands that a preformed covering for a stent is a tube.

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- 7) No claim is allowed.
- 8) Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

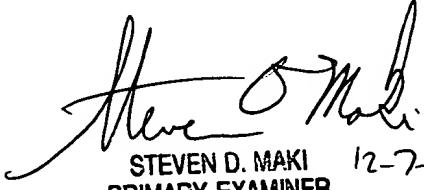
A shortened statutory period for response to this final action is set to expire THREE MONTHS from the date of this action. In the event a first response is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event will the statutory period for response expire later than SIX MONTHS from the date of this final action.

- 9) Any inquiry concerning this communication or earlier communications from the examiner should be directed to Steven D. Maki whose telephone number is (703) 308-2068. The examiner can normally be reached on Monday to Friday from 9:30 AM to 6:00 PM.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Ball, can be reached on (703) 308-2058. The fax phone number for Art Unit 1301 is (703) 305-7115. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0651.

Steven D. Maki
December 7, 1997


STEVEN D. MAKI 12-7-97
PRIMARY EXAMINER
GROUP 1300